

510(k) Summary
for the
Denali Deformity System

This safety and effectiveness summary for the Denali Deformity System is provided as required per Section 513(i)(3) of the Food, Drug and Cosmetic Act.

1. Submitter :

K2M, LLC
751 Miller Drive, SE
Suite F1
Leesburg, VA 20175

Contact Person :

Richard W. Woods
K2M, LLC
751 Miller Drive, SE, Suite F1
Leesburg, VA 20175
Telephone: 703-777-3155

MAY 23 2006

Date Prepared: August 29, 2005

2. Tradename:

Denali Deformity Spinal System

Common Name: Spine Fixation System

Classification Name: Pedicle Screw Spinal System (21 CFR 888.3070(b)(1))
Spinal Interlaminar Fixation Orthosis (21 CFR 888.3050)

3. Predicate or legally marketed devices which are substantially equivalent:

- Xia Spine System (Stryker Howmedica Osteonics)
- Denali Spine System (K2M, LLC)
- CD Horizon Legacy 5.5mm Spinal System (Medtronic Sofamor Danek)

4. Description of the device:

The Denali Deformity System is a top-loading, multiple component, posterior spinal fixation system which consists of pedicle screws, rods, locking set screws, offset connectors and transverse connectors. All of the components are available in a variety of sizes to match more closely the patient's anatomy.

Materials: The devices are manufactured from Ti6Al-4V ELI alloy per ASTM and ISO standards.

Function: The system functions as an adjunct to fusion to provide immobilization and stabilization of spinal segments of the thoracic, lumbar or sacral spine.

5. Intended Use:

The Denali Deformity System is a non-cervical spinal fixation device intended for posterior, non-pedicle fixation for the following indications: degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e. fracture or dislocation); spinal stenosis; curvatures (i.e. scoliosis, kyphosis; and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion.

The Denali Deformity System is also intended for non-cervical pedicle screw fixation for the following indications: trauma (i.e. fracture or dislocation); spinal stenosis; curvatures (i.e. scoliosis, kyphosis; and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion. It is also indicated for the treatment of severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

6. Comparison of the technological characteristics of the device to predicate and legally marketed devices :

The Denali Deformity System was biomechanically tested and compared to the predicate systems and other currently marketed systems and performed equal to or better than these systems in ASTM testing to F1717. The design features and sizing of the components were also compared and the Denali Deformity System found to be substantially the same as these systems. It is manufactured from the same FDA recognized materials and is indicated for the same intended uses as these systems. There are no significant differences between the Denali Deformity Spinal System and other systems currently being marketed which would adversely affect the use of the product. It is substantially equivalent to these other devices in design, function, material and intended use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 23 2006

K2M, L.L.C.
c/o Mr. Richard W. Woods
Senior Vice President
751 Miller Dr., SE, Suite F-1
Leesburg, Virginia 20175

Re: K052404

Trade/Device Name: Denali Deformity System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle Screw Spinal System
Regulatory Class: Class II
Product Code: MNI, MNH, KWP
Dated: April 24, 2006
Received: April 26, 2006

Dear Mr. Woods:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Mr. Richard W. Woods

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



for

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use510(k) Number (if known): K052404Device Name: Denali Deformity System**Indications for Use:**

The Denali Deformity System is a non-cervical spinal fixation device intended for posterior, non-pedicle fixation for the following indications: degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e. fracture or dislocation); spinal stenosis; curvatures (i.e. scoliosis, kyphosis; and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion.

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Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-the-counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS-LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)**Division of General, Restorative,
and Neurological Devices**510(k) Number K052404